

## REMARKS

In the Office Action, the drawings are objected to; claims 13, 14 and 19-22 are rejected under 35 U.S.C. § 112, second paragraph; and claims 1-38 are rejected under 35 U.S.C. § 102 and/or under 35 U.S.C. § 103. Claim 13 has been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons as set forth below.

At the outset, the drawings are objected to as previously discussed. In response, Applicants are submitting herewith Figure 4 on one sheet as attached and also have amended the specification as previously discussed. Applicants believe that newly submitted Figure 4 and the changes to the specification are responsive to the drawing objection and therefore respectfully submit that the drawings are in compliance with 37 C.F.R. § 1.83. Accordingly, Applicants respectfully request that the drawing objection be withdrawn.

In the Office Action, claims 13, 14 and 19-22 are rejected under 35 U.S.C. § 112, second paragraph. The Patent Office essentially alleges that the claims at issue are indefinite.

In response, claim 13 has been amended to recite that the apparatus of claim 11 further comprises a sterile pad such that the capacity sensor detects wetness due to blood loss into the sterile pad overlying a vascular access region of a venous needle. Claim 19 recites the apparatus of claim 17 further comprising a sterile pad overlying an access region of the venous needle such that the sensor detects wetness in the sterile pad due to blood loss from the patient upon venous needle dislodgement. Thus, Applicants believe that claims 13 and 19 each positively recite the sterile pad feature as claimed.

Claim 14 depends from claim 13 and claims 20-22 depend from claim 19. Therefore, as a matter of law, these claims incorporate the features of their respective base claims from which they depend. In view of same, Applicants believe that claims 13, 14 and 19-22 satisfy the requirements under 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1, 2, 7-10, 15, 17, 18 and 23-26 are rejected under 35 U.S.C. § 102. The Patent Office essentially asserts that the features, as defined in the claims at issue, are allegedly disclosed in WO 99/24145. Applicants believe that this rejection is improper and should be withdrawn.

Of the pending claims, claims 1, 15 and 17 are the sole independent claims at issue. Claim 1 recites an apparatus for detecting dislodgement of a needle inserted into a patient. The apparatus includes a sensor capable of detecting wetness due to blood; and a sensor holder adapted to secure the sensor in juxtaposition to the needle such that the sensor detects wetness due to blood loss from the patient upon dislodgement of the needle. Claim 15 recites an apparatus for detecting dislodgement. The apparatus includes a resistive sensor that is capable of detecting wetness due to blood wherein the resistive sensor includes at least two electrodes. The apparatus further includes a sensor holder that defines an interior for receiving at least a portion of the needle and coupling the resistive sensor to the patient such that the resistive sensor is capable of detecting the blood loss due to dislodgement of the needle. Claim 17 recites an apparatus for controlling blood loss from the patient during hemodialysis. The apparatus includes a sensor that is capable of detecting wetness due to blood and a sensor holder that is adapted to secure the sensor to the patient such that the sensor produces a signal indicative of wetness due to blood loss from the patient upon dislodgement of a venous needle inserted into the patient. The apparatus further includes a controller capable of processing the signal to prevent blood flow through the venous needle such that blood loss from the patient due to dislodgement of the venous needle is minimized.

In contrast, Applicants believe the cited art is deficient with respect to the claimed invention. For example, Applicants believe that the cited art at least fails to disclose or arguably suggest the apparatus that includes a sensor adaptedly secured to the needle with the sensor holder as required by the claimed invention. As disclosed in the specification, the sensor holder can act to shield and protect the sensor, needle and other components that it covers in addition to properly positioning and securing the sensor over the access or insertion region of the needle. This can ensure that the sensor effectively acts to detect the presence of needle dislodgement. See, Specification, page 8, lines 4-8 and as further illustrated in Fig. 1.

The cited art merely discloses a pair of sensors that may be secured to the patient with an adhesive patch 40 or a wrap-around cuff-like member 50 as shown in Figures 2 and 3, for example. This clearly contrasts the claimed invention that includes, in part, a sensor that is secured by the sensor holder which can act to shield and protect the sensor and other components in addition to securing the sensor in place for effective use as previously discussed. Indeed, the

adhesive patch 40 and the wrap-around cuff-like member 50 merely cover a tip portion of the needle as disclosed in Figures 2 and 3, for example, of the cited art.

Based on at least these differences, Applicants believe that the cited art and the claimed invention are distinguishable. Therefore, Applicants respectfully submit that the cited art fails to disclose or arguably suggest the claimed invention as defined by claims 1, 2, 7-10, 15, 17, 18 and 23-26.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, claims 27-29, 30-34, 36 and 37 are rejected under 35 U.S.C. § 103. The Patent Office essentially asserts that WO 99/24145 discloses or suggests the claimed invention as defined by the claims at issue. Applicants believe that this rejection is improper.

Of the pending claims at issue, claims 27, 30 and 36 are the sole independent claims. Claim 27 recites a method of detecting needle dislodgement that includes the steps of providing a sensor capable of detecting wetness due to blood; inserting a needle into a patient; and securing the sensor to the patient such that the sensor detects blood on the patient upon dislodgement of the needle. Claim 30 recites a method of controlling blood loss from a patient due to needle dislodgement. The method of claim 30 recites the steps of providing the sensor that is capable of detecting wetness due to blood; inserting a needle into the patient; and securing the sensor to the patient such that the sensor produces a signal indicative of wetness due to blood loss from the patient upon dislodgement of the needle; and processing the signal to prevent blood flow through the venous needle such that blood loss from the patient due to needle dislodgement is minimized.

Claim 36 recites a method of providing dialysis to a patient. The method includes providing a sensor that is capable of detecting wetness due to blood; inserting a venous needle into the patient; securing the sensor in juxtaposition to the venous needle; passing blood through the venous needle via a hemodialysis machine; and detecting blood loss from the patient upon dislodgement of the venous needle. As previously discussed, the sensor as claimed is secured in place such that the sensor and/or other components are protected in addition to being held securely in place such that dislodgement detection can be effectively provided. This is illustrated in Figure 1 of the present application and further in Figures 3A to 3C.

Applicants believe that the cited art is deficient with respect to the claimed invention. Indeed, the cited art merely discloses an adhesive patch or a cuff-like member to secure the

sensor in place as previously discussed. Clearly, this is deficient with respect to the claimed invention that securely affixes the sensor to the patient while providing protection of same and thus allowing for effective dislodgement detection. Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art fails to render obviousness the claimed invention.

In the Office Action, claim 35 is rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 and further in view of WO 97/10013, Shintani et al. or JP 11-104233. The Patent Office essentially relies on a combination of references to remedy the deficiencies of WO 99/24145.

Applicants believe this rejection is improper for substantially the same reasons as discussed above. Claim 35 depends from claim 30, indirectly, and thus incorporates each of the features of claim 30. As previously discussed, the WO 99/24145 merely discloses an adhesive patch or cuff-like member to secure the sensor in place and thus for at least these reasons as clearly deficient with respect to the claimed invention.

Further, the Patent Office cannot rely merely on the remaining cited art to remedy the deficiencies of WO 99/24145. Indeed, the Patent Office merely relies on the remaining cited art for their alleged teaching relating to closing a control valve in response to blood leakage. Therefore, even if combinable, the cited art fails to render obvious the claimed invention as defined in claim 35.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 3, 4, 8, 9, 16, 19, 20, 22 and 25 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 in view of Cox et al. ("Cox"). The Patent Office essentially relies on Cox to remedy the deficiencies of WO 99/24145.

Applicants believe that this rejection is improper at least for substantially the same reasons as discussed above with respect to independent claims 1, 15 and 17. Indeed, the claims at issue depend from either of independent claims 1, 15 and 17 and therefore, as a matter of law, incorporate each of the features of their respective independent claims. As discussed above, the WO 99/24145 reference is clearly deficient with respect to the claimed invention as it merely suggests attaching the sensors to the patient with an adhesive patch or a cuff-like member.

Further, the Cox reference cannot be relied on solely to remedy the deficiencies of the primary reference. In this regard, the Patent Office merely relies on Cox for its alleged teaching regarding a loop-type resistive sensor. Therefore, even if combinable, the cited art is clearly deficient with respect to the claimed invention and thus fails to render obvious same.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 5, 6, 11-14 and 21 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 in view of Johnson. The Patent Office essentially relies on Johnson to remedy the deficiencies of the WO 99/24145 reference.

At the outset, Applicants question whether the WO 99/24145 and Johnson references can be combined in the first place. Indeed, the WO 99/24145 reference merely relates to a resistive-type sensor that is utilized to detect wetness from blood. In contrast, the sensor in Johnson is merely used to detect wetness in a diaper. Moreover, Johnson utilizes a capacitive detection where the sensor is not in contact with the wetness in the diaper that is detected.

This clearly contrasts the resistive-type sensors as disclosed in the WO 99/24145 reference, let alone the application thereof as directed to the detection of wetness due to blood in response to needle dislodgement. Clearly, the detection sensitivity with respect to a sensor as applied to diaper wetness in comparison to wetness due to blood in response to needle dislodgement are very different to the extent that one skilled in the art would not be so inclined to utilize the teachings of Johnson to modify what the WO 99/24145 reference allegedly discloses.

Assuming arguendo that these references are even combinable, the combination of same is still deficient with respect to the claimed invention. As previously discussed, the WO 99/24145 reference is clearly deficient with respect to the claimed invention as it merely discloses an adhesive patch or cuff-like member to secure the sensor in place. The claims at issue each depend from claims 1, 15 or 17, and thus, as a matter of law, incorporate each of the features of their respective independent claims.

Further, the Patent Office cannot merely rely on the Johnson reference to remedy the deficiencies of the primary reference. Indeed, the Patent Office merely relies on Johnson for its alleged teachings regarding a capacitive-type sensor. What the Patent Office clearly has done is

to apply hindsight reasoning to justify the combination and/or modification of the WO 99/24145 reference in view of Johnson. Of course, this type of obviousness analysis is clearly improper.

Based on at least these reasons, Applicants believe that the cited art is deficient with respect to the claimed invention. Even if combinable, Applicants believe that the cited art fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1, 2, 4, 5, 7-10, 15 and 16 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over Cox in view of WO 99/24145. The Patent Office essentially relies on the WO 99/24145 reference to remedy the deficiencies of Cox. At the outset, Applicants question whether these references can be combined in the first place. In this regard, the Patent Office relies on Cox as allegedly disclosing a capacitance-type blood sensor. However, this type of blood sensor is clearly not disclosed in the WO 99/24145 reference as even admitted by the Patent Office. See, Office Action, page 5, paragraph 12. As previously discussed, the primary focus of this reference relates to a resistive-type sensor that is secured to the patient by an adhesive patch or cuff-like member. Therefore, Applicants question why one skilled in the art would be inclined to modify the Cox disclosure with the resistive-type sensor features as allegedly disclosed in WO 99/24145.

Even if combinable, Applicants believe that the cited art is deficient with respect to the claimed invention. Indeed, the primary focus of Cox relates to a monitor for detecting external bleeding from a puncture site on a patient and not for detecting dislodgement of a needle, such as during dialysis as required by the claimed invention. See, *Cox*, Abstract.

Further, the Patent Office cannot merely rely on the WO 99/24145 reference to remedy the deficiencies of Cox. As previously discussed, this reference is clearly deficient with respect to the claimed invention where this reference merely discloses a sensor that is secured to the patient with an adhesive patch or cuff-like member. Therefore, even if combinable, the cited art fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

Applicants note for the record that the Examiner has cited to JP 11-104233 in the Notice of References Cited that was submitted with the Office Action. Applicants further note that this reference is equivalent to U.S. Patent No. 6,077,443 that was previously cited in Applicants'

Information Disclosure Statement that was filed on August 23, 2001. The Examiner has referred to the Applicant of JP 11-104233 as Reena. However, the Applicant name is Rainer Goldau and Applicants respectfully request that this change be indicated in the record.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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